## Remarks

Claims 1, 3, 6 and 12-15 were pending. No claims are cancelled. Claims 16-17 are added. Therefore, claims 1, 3, 6 and 12-17 are now pending.

Support for the amendments and new claims can be found throughout the specification, for example:

Claims 1 and 6: page 4, lines 18-24; page 11, line 33; and page 18, lines 10-11.

Claims 13 and 14: amended to remove redundant language.

Claims 16-17: page 12, line 28 – page 13, line 3; and page 18, lines 13-23.

No new matter has been added.

***Claim objections***

Claims 1 and 6 are objected to on the ground that the term "Japan (HVJ)" is unclear. Claims 1 and 6 are amended to recite "HVJ (hemagglutinating virus of Japan)-envelope vector."

In view of this amendment, Applicants request that the objection to claims 1 and 6 be withdrawn.

***Double Patenting Rejection***

Claims 1, 3, 6, and 12-15 are rejected under the judicially created obviousness-type double patenting as being unpatentable over claims 1, 2, 4 and 5 of U.S. Patent No. 6,936,594, in view of Hayashi *et al.* (*Gene Therapy* 8:1167-73, 2001) and Barnes *et al.* (*J. Lipid Res.* 28:130-7, 1987). Applicants disagree and request reconsideration.

Claims 1 and 6 are amended to distinguish the HVJ-liposome of the '594 patent and the claimed HVJ-envelope vector. Specifically, the claims now recite that the HVJ-envelope vector has a diameter that is less than that of an HVJ-liposome. As described on page 4, lines 18-24 of the specification, fusing HVJ to liposomes results in an average diameter that is 1.3 times that of an HVJ-viral particle. Further evidence of this difference in structure is provided in Dzau *et al.* (*Proc. Natl. Acad. Sci.* 93:11421-25, Exhibit A). For example, on page 11421, left column, last paragraph, it states that "Hemagglutinating virus of Japan (HVJ....) is 300 nm in diameter..." and on page 11421, right column, lines 31-34, it states fusion of "liposomes with UV-inactivated

HVJ to form fusiogenic viral liposomes containing DNA (400-500 nm in diameter)." Therefore, the liposome increases the diameter of the HVJ. New claims 16 and 17 further provide the method by which the HVJ-envelope vector is prepared, which results in a structure distinct from the HVJ liposome in the '594 patent. Thus, the claimed HVJ-envelope vector is structurally patentably distinct from the HVJ-liposome claimed in the '594 patent.

Therefore, Applicants request that the double-patenting rejection be withdrawn.

**35 U.S.C. §112, first paragraph (new matter)**

Claims 1, 3, 6 and 12-15 are rejected as new matter under 35 U.S.C. §112, first paragraph due to the recitation "free of liposome." Applicants request reconsideration.

Claims 1 and 6 are amended to remove the recitation "free of liposome."

In view of this amendment, Applicants request that the 35 U.S.C. §112, first paragraph new matter rejection be withdrawn.

**35 U.S.C. §112, first paragraph (enablement)**

Claims 6, 12, 14 and 15 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Applicants disagree and request reconsideration.

Claim 6 is amended to remove the phrase "prior to the occurrence of said cerebral infarction." The claims are enabled for a method of reducing an infracted area of a cerebral infarction by administering the claimed HVJ-envelope vector to the subarachnoid space (FIG. 4). Applicants have demonstrated in an animal model that the method works as claimed. There is no requirement for human clinical data to obtain method of treatment claims. In fact, MPEP § 2107.03 states that "Office personnel should not impose on applicants the unnecessary burden of providing evidence from human clinical trials."

Claims 1 and 6 are amended to recite "vector…operably linked to a promoter," as suggested by the Examiner. Support can be found from the working example in the specification (see page 18, lines 10-11, wherein the pVAX1 vector is known to have a CMV promoter, see Exhibit B).

In view of these amendments, Applicants request that the 35 U.S.C. §112, first paragraph enablement rejection be withdrawn.

**35 U.S.C. §112, second paragraph**

Claims 1, 3, 6, and 12-15 are rejected as indefinite under 35 U.S.C. §112, second paragraph. Applicants request reconsideration.

It is asserted that the phrases "hemagglutinating virus of Japan (HVJ)-envelope vector" and "free of liposome" are unclear. Claims 1 and 6 are amended to clarify that the vector is what is claimed, and the phrase "free of liposome" has been deleted.

In view of these amendments, Applicants request that the 35 U.S.C. §112, second paragraph rejection be withdrawn.

**35 U.S.C. §102(b)**

Claims 1, 3, 6, and 12-15 are rejected under 35 U.S.C. §102(b) as anticipated by Morishita *et al.* (Australian Patent Appl. No. 200073148 B2, published on April 24, 2001, now Patent No. 774990) as evidenced by Hayashi *et al.* (*Gene Therapy*, 8:1167-73, 2001) and Barnes *et al.* (*J. Lipid Res.*, 28:130-7, 1987). In addition, claims 1, 3, 6, and 12-15 are rejected as anticipated by Hayashi *et al.* as evidenced by Barnes *et al.*. Applicants disagree and request reconsideration.

As discussed above, claims 1 and 6 are amended to clarify the structure of the HVJ-envelope vector, so as to clarify the difference between the claimed vector and the HVJ-liposome of the '594 patent. Specifically, the claims now recite that the HVJ-envelope vector has a diameter that is less than that of an HVJ-liposome. Thus, the claimed HVJ-envelope vector is structurally patentably distinct from the HVJ-liposome claimed in the '594 patent.

In view of the amendments to claims 1 and 6, Applicants request that the 35 U.S.C. § 102(b) rejections be withdrawn.

***35 U.S.C. §102(e)***

Claims 1, 3, 6, and 12-15 are rejected under 35 U.S.C. §102(e), as anticipated by Morishita *et al.* (US Patent No.6,936,594) as evidenced by Hayashi *et al.* (*Gene Therapy,* 8:1167-73, 2001) and Barnes *et al.* (*J. Lipid Res.*, 28:130-7, 1987). Applicants disagree and request reconsideration.

As discussed above, claims 1 and 6 are amended to clarify the structure of the HVJ-envelope vector, so as to clarify the difference between the claimed vector and the HVJ-liposome

of the '594 patent. Specifically, the claims now recite that the HVJ-envelope vector has a diameter that is less than that of an HVJ-liposome. Thus, the claimed HVJ-envelope vector is structurally patentably distinct from the HVJ-liposome claimed in the '594 patent.

In view of the amendments to claims 1 and 6, Applicants request that the 35 U.S.C. § 102(e) rejections be withdrawn.

If any minor issues remain before a Notice of Allowance is issued, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

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